BARNES & THORNBURG

11 South Meridian Street Indianapolis, Indiana 46204 (317) 236-1313 (317) 231-7433 Fax

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group:	Unknown	}
Confirmation No.:	Unknown	} }
Application No.:	Unknown	}
Invention:	REINFORCED SMALL INTESTINAL SUBMUCOSA (SIS)	} } }
Applicant:	Plouhar et al.	} }
Filed:	September 05, 2003 (herewith)	}
Attorney Docket:	265280- 73406	}
Examiner:	Unknown	}

<u>INFORMATION DISCLOSURE STATEMENT</u>

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This statement is filed in the application identified above pursuant to 37 C.F.R. § 1.56. No representation is intended that a complete search has been made of the prior art or that no better art references than listed below are available. The filing of this Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in §1.56(b).

All listed references were cited during prosecution of parent U.S. Application Serial No. 09/918,116 filed July 30, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Therefore, copies of the references are not required pursuant to 37 C.F.R. § 1.98(d).

None of the cited art is believed to disclose or suggest the invention recited in the claims of the above-identified application. It is therefore believed that the claimed invention is patentably distinguishable over these references.

Please charge any fees that might be due in connection with this Information Disclosure Statement to our Deposit Account No. 10-0435, with reference to our matter 30298-72742. An extra copy of this Information Disclosure Statement is enclosed for that purpose.

Respectfully submitted, BARNES & THORNBURG

Jill^bT. Powlick Reg. No. 42,088

Indianapolis, Indiana (317) 231-7504

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 265280-73406

SERIAL No. Unknown

APPLICANT Plouhar et al.

FILING DATE

GROUP

				Sept. 5, 2003		Unknown	— F— = — = — = —	
J.S. PATENT	DOCUM	T	Data.	l N	01	Contrata	l succession	
Examiner Initial	——	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate	
	AA	3,562,820	Feb. 16, 1971	B. Braun		ļ		
	AB	4,400,833	Aug. 20, 1983	Kurland		<u> </u>		
	AC	4,902,508	Feb. 20, 1990	Badylak et al.		<u> </u>		
	AD	4,956,178	Sep. 11, 1990	Badylak et al.		<u> </u>		
 	AE	5,275,826	Jan. 4, 1994	Badylak et al.				
	AF	5,281,422	Jan. 25, 1994	Badylak et al.				
	AG	5,352,463	Oct. 4, 1994	Badylak et al.				
	AH	5,372,821	Dec. 13, 1994	Badylak et al.				
	AI	5,445,833	Aug. 29, 1995	Badylak et al.		<u> </u>		
	AJ	5,516,533	May 14, 1996	Badylak et al.				
v 1	AK	5,554,389	Sep. 10, 1996	Badylak et al.		<u> </u>		
OREIGN PA	TENT DO	CUMENTS						
		Document Number	Date	Country	Class	Subclass	Translation Yes No	
	AL	WO 97/37613	Oct. 16, 1997	PCT				
	AM	WO 00/16822	Mar. 30, 2000	PCT				
	AN	EP 0 446 105 A2	Jan. 15, 1992	EPO				
	AO	EP 0 734 736 A1	Oct. 2, 1996	EPO				
	AP	}						
OTHER REFE	AQ	of Biomedical Materials	l properties of xenoge Research, Vol. 29, 88	neic small-intestinal submud 33-891, (1995)				
	AR	Sandusky, et al., "Healing Comparison of Small Intestine Submucosa and ePTFE Grafts in the Canine Carotid Artery", J. Surg.Res., 58:415-420, (1995)						
	AS	Knapp, et al., "Biocompatibility of Small-Intestine Submucosa in Urinary Tract as Augmentation Cystoplasty Graft and Injectable Suspension", <i>J Endourology</i> , 8:125-130, (1994)						
	AT	Kropp et al., "Regenerative Bladder Augmentation: A Review of the Initial Preclinical Studies with Porcine Small Intestinal Submucosa", Muscle, Matrix, and Bladder Function. Plenum Press, New York, (1995)						
	AU	Kropp et al., "Experimental Assessment of Small Intestinal Submucosa as a Bladder Wall Substitute", Urology 446:396-400, (1995)						
	AV	Vaught et al., "Detrusor Regeneration in the Rat Using Porcine Small Intestinal Submucosa Grafts: Functional Innervation and Receptor Expression", J. Urol., 155:374-378, (1996)						
	AW	Kropp et al, "Characterization of Small Intestinal Submucosa Regenerated Canine Detrusor: Assessment of Reinnervation, In Vitro Compliance and contractility, <i>J. of Urol</i> ,156:599-607, (1996)						
	AX	Kropp et al., "Regenerative Urinary Bladder Augmentation Using Small Intestinal Submucosa: Urodynamic and Histopathologic Assessment in Long-Term Canine Bladder Augmentations", <i>Journal of Urology</i> , 155:2098-2104, (1996)						
	AY	Aiken et al., "Small Intestinal Submucosa as an Intra-Articular Ligamentous Graft Material: A Pilot Study in Dogs", Vet Comp Orthopedics Traumatology, 7:124-128, (1994)						
	AZ	Badylak et al., "The Use of Xenogeneic Small Intestinal Submucosa as a Biomaterial for Achille's Tendon Repair in a dog model", J Biomed Materials, 29:977-985, (1995)						
Examiner	4			·		Date Consi	dered	
EXAMINER:	Initial if rough citat	eference considered, whe	ther or not citation is i	n conformance with MPEP 6	509.	ation to applica	ant	

Sheet 2___of __4_

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

	ATTY. DOCKET NO. 265280-73406	SERIAL No. Unknown
	APPLICANT Plouhar et al.	
į	FILING DATE Sept. 5, 2003 (herewith)	GROUP Unknown

J.S. PATENT							
	DOCUM	ENTS					
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	BA	5,573,784	Nov. 12, 1996	Badylak et al.			
	ВВ	5,591,234	Jan. 7, 1997	Kirsch			
	ВС	5,593,441	Jan. 14, 1997	Lichtenstein, et al.			
	BD	5,641,518	Jun. 24, 1997	Badylak et al.			
	BE	5,645,860	Jul. 8, 1997	Knapp, Jr. et al.			
	BF	5,668,288	Sep. 16, 1997	Storey et al.			
	BG	5,693,085	Dec. 2, 1997	Buirge, et al.			
	ВН	5,695,998	Dec. 9, 1997	Badylak et al.			
	_BI	5,711,969	Jan. 27, 1998	Patel et al.			
	BJ	5,730,933	Mar. 24, 1998	Peterson			
	вк	5,733,868	Mar. 31, 1998	Peterson et al.			
FOREIGN PA	TENT DO	CUMENTS_					
		Document Number	Date	Country	Class	Subclass	Translation Yes No
	BL						
	вм						
	BN						
	ВО						ļ
A-1							
OTHER REF	ERENCES	(Including Author, Title,	Date, <u>Pertinent Pag</u> es	s, Etc.)			
OTHER REF	BQ	Hodde et al., "The Effect	t of Range of Motion	s, <i>Etc.)</i> Upon Remodeling of Small Ir e <i>Engineering</i> 3, 1:27-37, (19		cosa (SIS) who	en used as an Achille
OTHER REF		Hodde et al., "The Effect Tendon Repair Material	t of Range of Motion in the Rabbit", <i>Tissue</i>	Upon Remodeling of Small In	97)		
OTHER REF	BQ	Hodde et al., "The Effect Tendon Repair Material Ferrand et al., "Directio	et of Range of Motion in the Rabbit", <i>Tissue</i> nal Porosity of Porcine	Upon Remodeling of Small In Engineering 3, 1:27-37, (19	97) a", <i>J Biomed Ma</i>	iterials Res, 27	7:1235-1241, (1993)
OTHER REF	BQ BR	Hodde et al., "The Effect Tendon Repair Material Ferrand et al., "Directio Hiles et al., "Porosity of 144, (1993)	et of Range of Motion in the Rabbit", Tissue nal Porosity of Porcine Porcine Small-Intestination of the Small Content of the Small Cont	Upon Remodeling of Small In e Engineering 3, 1:27-37, (19 e Small-Intestinal Submucosa	97) s", <i>J Biomed Ma</i> Vascular Graft",	iterials Res, 27	7:1235-1241, (1993) erials Res, 27: 139-
OTHER REF	BQ BR BS	Hodde et al., "The Effect Tendon Repair Material Ferrand et al., "Directio Hiles et al., "Porosity of 144, (1993) Hodde et al., "Glycosan Engineering, 2:3, 209-2	et of Range of Motion in the Rabbit", Tissue nal Porosity of Porcine Porcine Small-Intestin ninoglycan Content of 17, (1996)	Upon Remodeling of Small In e Engineering 3, 1:27-37, (19 e Small-Intestinal Submucosa nal Submucosa for use as a \	97) a", <i>J Biomed Ma</i> Vascular Graft", A Bioscaffold f	oterials Res, 27 J Biomed Mat or Tissue Repl	7:1235-1241, (1993) erials Res, 27: 139- acement", Tissue
OTHER REF	BQ BR BS BT	Hodde et al., "The Effect Tendon Repair Material Ferrand et al., "Direction Hiles et al., "Porosity of 144, (1993) Hodde et al., "Glycosan Engineering, 2:3, 209-2 Prevel et al., "Small Inte 380, (1995)	et of Range of Motion in the Rabbit", Tissue nal Porosity of Porcine Porcine Small-Intestinationally can Content of 17, (1996) estinal Submucosa: University of Motion 17, (1996)	Upon Remodeling of Small In e Engineering 3, 1:27-37, (19the e Small-Intestinal Submucosa nal Submucosa for use as a N Small Intestinal Submucosa:	97) a", <i>J Biomed Ma</i> Vascular Graft", A Bioscaffold f	J Biomed Mat or Tissue Repl	erials Res, 27: 139- acement", Tissue
OTHER REF	BQ BR BS BT BU	Hodde et al., "The Effect Tendon Repair Material Ferrand et al., "Direction Hiles et al., "Porosity of 144, (1993) Hodde et al., "Glycosan Engineering, 2:3, 209-2 Prevel et al., "Small Inte 380, (1995) Clarke et al., "Intestine (1996)	et of Range of Motion in the Rabbit", Tissue nal Porosity of Porcine Porcine Small-Intestil ninoglycan Content of 17, (1996) estinal Submucosa: Usestinal Su	Upon Remodeling of Small Interpretation of Rodent Interpretation of Repair of Rodent Interpretation of Rodent Interpretation of Repair of Rodent Interpretation of Repair of Rodent Interpretation of Rodent Interpretation Interpretat	97) a", <i>J Biomed Ma</i> Vascular Graft", A Bioscaffold f Abdominal Wa	J Biomed Mat or Tissue Repl II Defects", And	erials Res, 27: 139- acement", Tissue n Plast Surg, 35:374 g Res, 60:107-114,
OTHER REF	BQ BR BS BT BU BV	Hodde et al., "The Effect Tendon Repair Material Ferrand et al., "Directio Hiles et al., "Porosity of 144, (1993) Hodde et al., "Glycosan Engineering, 2:3, 209-2 Prevel et al., "Small Inte 380, (1995) Clarke et al., "Intestine (1996) Prevel et al., "Small Inte Surg. 35:381-388, (199	et of Range of Motion in the Rabbit", Tissue nal Porosity of Porcine Porcine Small-Intestinational Porcine Small-Intestination (1996) estinal Submucosa: University of Porcine Submucosa: University o	Upon Remodeling of Small Interpretation of Rodent propylene Mesh for Abdomination of Small Interpretation of Rodent propylene Mesh for Abdomination of Rodent Interpretation Interpr	97) a", <i>J Biomed Ma</i> Vascular Graft", A Bioscaffold f Abdominal Wa al Wall Repair in	J Biomed Mat or Tissue Repl II Defects", And on Dogs", J Surgess Rodent W	erials Res, 27: 139- acement", Tissue in Plast Surg, 35:374 g Res, 60:107-114, ounds", Ann Plast
OTHER REF	BQ BR BS BT BU BV BW	Hodde et al., "The Effect Tendon Repair Material Ferrand et al., "Direction Hiles et al., "Porosity of 144, (1993) Hodde et al., "Glycosan Engineering, 2:3, 209-2 Prevel et al., "Small Inte 380, (1995) Clarke et al., "Intestine (1996) Prevel et al., "Small Inte Surg. 35:381-388, (1996)	et of Range of Motion in the Rabbit", Tissue nal Porosity of Porcine Porcine Small-Intestinational Porcine Small-Intestinational Submucosa: University of Porcine Small-Intestinational Submucosa: University of Porcine Small Sm	Upon Remodeling of Small Interpretation of Repair of Rodent propylene Mesh for Abdominatilization as a Wound Dressin	97) a", <i>J Biomed Ma</i> Vascular Graft", A Bioscaffold f Abdominal Wa al Wall Repair in g in Full-Thickn	J Biomed Mat or Tissue Repl II Defects", And on Dogs", J Surgess Rodent W	r:1235-1241, (1993) erials Res, 27: 139- acement", Tissue In Plast Surg, 35:374 g Res, 60:107-114, ounds", Ann Plast
OTHER REF	BQ BR BS BT BU BV BW BX	Hodde et al., "The Effect Tendon Repair Material Ferrand et al., "Direction Hiles et al., "Porosity of 144, (1993) Hodde et al., "Glycosan Engineering, 2:3, 209-2 Prevel et al., "Small Inte 380, (1995) Clarke et al., "Intestine (1996) Prevel et al., "Small Inte Surg. 35:381-388, (1996) Cobb et al., "Histology and Cobb et al., "Porcine Sr	et of Range of Motion in the Rabbit", Tissue nal Porosity of Porcine Porcine Small-Intestit ninoglycan Content of 17, (1996) estinal Submucosa: Usestinal Su	Upon Remodeling of Small Interpretation of Repair of Rodent propylene Mesh for Abdominatilization as a Wound Dressin th Small Intestinal Submucos	97) a", J Biomed Ma Vascular Graft", A Bioscaffold f Abdominal Wa al Wall Repair in g in Full-Thickn a", Surgical Ne	J Biomed Materials Res, 27 J Biomed Materials Replay or Tissue Replay Il Defects", And n Dogs", J Surgess Rodent W urology, 46: 38 gy, 51:99-104,	r:1235-1241, (1993) erials Res, 27: 139- acement", Tissue In Plast Surg, 35:374 g Res, 60:107-114, ounds", Ann Plast 19-394, (1996) (1999)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO. 265280-73406		SERIAL No. Unknown			
INFORMATION DISCLOSURE STATEMENT				APPLICANT Plouhar et al.					
				FILING DATE Sept. 5, 2003 (herewith)		GROUP Unknown			
U.S. PATENT I	ООСИМ	ENTS							
*Examiner Initial		Document Number	Date	Name Class		Subclass	Filing Date if Appropriate		
	CA	5,735,897	Apr. 7, 1998	Buirge					
	СВ	5,753,267	May 19, 1998	Badylak	Badylak et al.				
	СС	5,755,791	May 26, 1998	Whitson et al.					
	CD	5,759,205	Jun. 2, 1998	Valentini					
	CE	5,762,966	Jun. 9, 1998	Knapp et al.					
	CF	5,788,625	Aug. 4, 1998	Plouhar et al.					
	CG	5,855,613	Jan. 5, 1999	Antanav	Antanavich, et al.				
	СН	5,866,414	Feb. 2, 1999	Badylak	Badylak et al.				
	CI	5,885,619	Jan. 5, 1999	Caplan,	et al.	-			
	CJ	5,922,028	Jul. 13, 1999	Plouhar	et al.				
	СК	5,989,2804	Nov. 23, 1999	Euteneu	er, et al.				
FOREIGN PAT			<u> </u>	L	<u> </u>		L	<u> </u>	
I OILEION I / / I		Document Number	Date	Cou	Country Class		Subclass	Translation Yes No	
	CL								
	СМ								
	CN								
	СО			}					
	СР								
OTHER REFEI	RENCES	(Including Author, Title, D	ate. Pertinent Pages.	. Etc.)					
	CR	Suckow, M.A., "Enhar 277, (1999)			ng Porcine Small I	ntestinal S	ubmucosa",	J. Invest Surg, 12:	
	cs	Badylak , S., et al., "Naturally Occurring Extracellular Matrix as a Scaffold for Musculoskeletal Repair", Clin Orthop, 3675:S333-S3433, (1999)							
	СТ	Cook, J.L. et al., "Induction of Meniscal Regeneration in Dogs Using a Novel Biomaterial", <i>Am J Sports Med</i> , 27: 658, (1999)							
	CU	Dejardin, L.M. et al., "Use of small intestinal submucosal implants for regeneration of large fascial defects: an experimental study in dogs", J Biomed Mater Res, 46:203-211, (1999)							
-	CV	Sacks, M.S., et al., "Quantification of the fiber architecture and biaxial mechanical behavior of porcine intestinal submucosa", <i>J Biomed Mater Res</i> , 46:1-10, (1999)							
	CW	COOK® News Releases, "COOK® Introduces Innovative Surgisis™ Soft Tissue Repair Biomaterial", (5/21/00)							
	сх	COOK® News Releases, "COOK® Oasis™ Wound Dressing Biomaterial From COOK® Remodels Partial Thickness Skin Injuries", (December 23, 1999)							
	CY	COOK® News Releases, "Cook Incorporated Forms Dedicated Tissue Engineered Products Group", (February 16, 2000)							
, , , , , , , , , , , , , , , , , , ,	cz	COOK® News Release Skin Injuries*, (Januar	ses, "FDA Clears C ry 24, 2000)	asis™ Wo	ound Dressing Bior	naterial Fro	om COOK®	For Full-Thickness	
Examiner							Date Consid	dered	
*EXAMINER: I Draw line throu	nitial if re ugh citati	eference considered, whet on if not in conformance a	her or not citation is in not considered. In	n conformat	nce with MPEP 609. of this form with nex	t communica	ation to applica	ant.	

Sheet 4__of 4

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE ATTY. DOCKET NO. 265280-73406 SERIAL No. Unknown APPLICANT Plouhar et al. INFORMATION DISCLOSURE STATEMENT FILING DATE Sept. 5, 2003 (herewith) **GROUP** Unknown **U.S. PATENT DOCUMENTS** Class Filing Date if Appropriate *Examiner Initial **Document Number** Date Name Subclass 6,027,744 Feb. 22, 2000 Vacanti, et al. DA 6,056,777 May 2, 2000 McDowell DB May 9, 2000 6,060,640 Pauley et al. DC 6,099,567 Aug. 8, 2000 Badylak et al. DD Jan. 9, 2001 6,171,344 Atala DE 6,176,880 B1 Jan. 23, 2001 Plouchar, et al. DF Jul. 10, 2001 6,258,124 B1 Darois, et al. DG 6,270,530 B1 Aug. 7, 2001 Eldridge, et al. DH 6,383,221 B1 May 7, 2002 Scarborough et al. DΙ 6,409,764 B1 Jun. 25, 2002 White, et al. DJ 6,497,650 B1 Dec. 24, 2002 Nicolo DK FOREIGN PATENT DOCUMENTS Document Number Date Class Subclass Country Translation Yes No DL DΜ DN. DO DP OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.) DR DS DT DU DV DW DX DY DΖ Examiner **Date Considered** *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.